

REMARKS

With this response to the Office Action, claims 1-38 are pending. Claims 9-11 and 19-25 are withdrawn from consideration. Claims 1, 3, 12, 15, 16 and 18 are rejected and 2, 4-8, 13, 14, 17 and 26-28 are objected to. The Applicant is adding claims 29-38.

Election/Restriction

Claims 9-11, 19, 21-25, 20 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected without traverse invention as note in paper number 10.

Typographical Errors

The Applicant has amended claims 13-18 to depend from independent claim 12 rather from independent claim 1. Claims 13-18 refer to "The implantable drug delivery device" and a proper antecedent basis is established by claim 12.

The Applicant has amended claims 26-28 depend from claim 23 rather than claim 14. Claims 26-28 refer to "The method for controlling an implantable drug delivery device" and a proper antecedent basis is established by claim 23.

Rejections under 35 USC §103

Claims 1, 3, 15, 16, 18 are rejected under 35 USC §103(a) as being unpatentable over Nappholz et al. (US Patent 5,188,106) in view of Wojcicki et al (US Patent 5,190,522). Regarding independent claim 1, the Office Action admits that "Nappholz does not disclose a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined". The Office Action alleges that Wojcicki makes up for the deficiency of Nappholz to have a nonconformance management module. The Office Action further alleges that the motivation to modify the teachings of Nappholz with the teachings of Wojcicki is "to have an accurate monitoring system and guarantees that the drug infused into the body of the patient" (Wojcicki, column 4, lines 3-6). The Applicant submits that a proper motivation to combine Wojcicki with Nappholz has not been presented by the Office Action, and thus prima facie obviousness has not been established. Regarding claim 1, the nonconformance monitor module is configured to monitor at least one performance parameter. The nonconformance monitor module (not the nonconformance management module) determines whether or not the monitoring system is

accurate or not. Consequently, the nonconformance management module is correspondingly irrelevant.

Claims 3, 15, 16, 18 ultimately depend from claim 1 and are patentable for at least the above reasons. Thus, the Applicant requests for reconsideration of claims 1, 3, 15, 16, and 18.

Rejections under 35 USC §102

Claim 12 is rejected under 35 USC §102(b) as being anticipated by Wojcicki, et al. (US Patent 5,190,522). However, in accordance with MPEP § 2131, "To anticipate a claim, the reference must teach every element of the claim." The Applicant submits that Wojcicki does not. Claim 12 includes the feature of "memory having stored therein pump performance acquisition instructions". The present patent application discloses (paragraph 50):

As shown in the block diagram of Figure 10, the nonconformance management module 115 includes a nonconformance management algorithm 825 that gathers information including the pump performance data regarding the implantable device 105, drug management data 815, pump manufacturer requirements 820, and patient performance requirements 825. **Provided back to the implantable drug delivery device 105 from the external device 110 are pump performance acquisition instructions 810 that provide information about the particular pump performance data information that needs to be gathered.**

In contrast, Wojcicki, at the location identified as relevant by the Examiner, discloses (Column 4, lines 31-33):

an analyzing and control system which compares the measured parameters and the calculated amplitude with preset values recorded in memory.

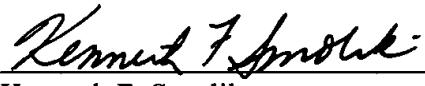
Accordingly, Wojcicki merely teaches that the memory contains preset values, not information regarding which performance data to be acquired. Thus, Wojcicki does not teach "memory having stored therein pump performance acquisition instructions" and thus does not anticipate claim 12. The Applicant requests reconsideration of claim 12.

Allowable Subject Matter

"Claims 2, 4, 5-8, 13, 14, 26-28 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims". The Applicant wishes to point out that claims 26-28 have been amended by this response to depend from claim 23 rather than from claim 14 and that claims 13, 14, and 17 depend from claim 12 rather than from claim 1.

The Applicant is adding claims 29-38, which are supported by the specification as originally filed. The Applicant respectfully submits that the instant application is in condition for allowance. Should the Examiner believe that a conversation with Applicant's representative would be useful in the prosecution of this case, the Examiner is invited and encouraged to call Applicant's representative.

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